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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,019	12/26/2001	Roland Henri Contreras	JAB-1521	5960

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EXAMINER	
ALLEN, MARIANNE P	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 10/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,019	CONTRERAS ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) *2-9,11-16,23,24 and 29-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,10,17-22,25-28 and 49-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-55* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant is advised that the status of claim 18 is incorrectly listed as withdrawn. This claim is pending and under consideration.

Election/Restrictions

The restriction requirement was made final in the prior Office action. The claims as originally filed lacked a special technical feature. As set forth in the prior Office action, the special technical feature argued by applicant is not found in all of the pending claims. It is noted that claim 1 as amended still refers to SEQ ID NO: 2. This sequence has not been examined.

Claim Rejections - 35 USC § 101/112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 10, 17-22, 25-28, and 49-53 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility.

Applicant points out that the prior Office action indicates upregulation rather than down regulation for this sequence. This inadvertent error is corrected in the following discussion but does not change the essential nature of the rejection.

SEQ ID NO: 285 is a 1229 nucleotide DNA sequence from *Candida albicans*. It encodes the 409 amino acid sequence of SEQ ID NO: 286. (See Figure 2.) Table 1 on page 37 (and as explained on page 27) indicates that YPR102C (corresponding to SEQ ID NO: 285) is downregulated as a result of *Bax*-induced cell death (see page 32, lines 15-20, of the specification). No other information is provided.

Neither SEQ ID NO: 285 nor 286 have been disclosed as having any similarity to known sequences with known function. The particular pathway that SEQ ID NOS: 285-286 are involved with in the *Bax*-induced cell death is not disclosed. It is unknown how or why the downregulation is caused or what effect such downregulation has. The particular role of these sequences is not disclosed. As such, one would not know how to use these sequences in any specific and substantial capacity without further experimentation. Further characterization of the sequence with respect to its biological activity or function would be required.

Applicant argues that the claimed sequence can be employed as a selective target for drugs to treat infections caused by or associated with yeast fungi or for the treatment of proliferative disorders for the prevention of apoptosis in certain diseases. (See page 17 of the response.) This is not persuasive. Differential expression of this or any other sequence disclosed would not be considered by a person of skill in the art sufficient information to use that sequence as a selective target for drugs as set forth above. At best, it might suggest performing further research to characterize the role of these sequences in the disease states of interest. However, the necessity for further characterization and experimentation to confirm or develop such an application does not meet the standard for utility. The claimed sequences have not been shown to provide a specific benefit in the form available at the time of the invention. Furthermore, this argument does not provide a use for the claimed sequences that are not the actual sequence (i.e. having only a certain percentage similarity, functional equivalents, degenerate sequences).

Claims 1, 10, 17-22, 25-28, and 49-53 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific,

substantial, and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

This rejection is maintained for reasons of record and as discussed above.

Claims 1, 10, 17-22, 25-28, and 49-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection and written description rejection.

Claim 1 has been amended to recite "wherein expression of said nucleic acid molecule is varied by a factor of 5 or more as a result of Bax-induced cell death." While the specific nucleic acids set forth in the claim (e.g. SEQ ID NO: 285) were identified by this expression criteria, there is no disclosure or contemplation of all nucleic acids encoding the amino acid sequences as set forth in the claims (e.g. all sequences encoding SEQ ID NO: 286) having this expression level. There is no disclosure or contemplation of those nucleic acids having more than 70%, 80%, 90%, or 97% similarity or identity having this expression level. There is no disclosure or contemplation of functional equivalents, derivatives, or bioprecursors having this expression level. There is no disclosure or contemplation of functional fragments or complements having this expression level. Finally, the Bax-induced cell death is not disclosed or contemplated with respect to any assay but rather mouse Bax-α induced cell death in yeast by using DNA encoding mouse Bax-α in a particular yeast plasmid. The limitation introduced in

claim 1 is more generic than this. Applicant's response does not appear to address this ground of rejection. Applicant is requested to point to the page and line number where the contemplation of sequences having the expression characteristics recited in the claims are set forth.

Again, even if this new matter rejection is overcome, claim 1 recites "functional fragment or complement thereof for the preparation of a medicament for treating diseases associated with yeast or fungi." The specification does not identify any such functional fragments or complements. No nucleic acid medicaments for treating any diseases associated with any yeast or fungi are disclosed. The structural identity of these sequences is not described. Likewise, no "functional equivalent, derivative or bioprecursor" sequences are disclosed. (See also claim 17 and dependent claims.) Claims 49 and 53 are directed to human homologues. The structural identity of such homologues are not disclosed. One of ordinary skill in the art has been provided with no criteria to determine if a particular sequence would be considered the human homologue. All of these sequences lack written description. Applicant's response does not appear to address this ground of rejection. Applicant is requested to point to the page and line number where the structure of sequences having the claimed characteristics are set forth such that one would envision the structure possessed by the claimed sequences.

Claims 1, 10, 17-22, 25-28, and 49-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 is indefinite for reciting SEQ ID NO. 2 that is not elected and withdrawn. Only SEQ ID NOS: 285 and 286 are under consideration.

Claim 1 recites "encoding a functional equivalent, derivative or bioprecursor." It is unknown from the specification what particular structural or functional characteristics define a functional equivalent, derivative or bioprecursor. See also claim 17. Applicant's response did not address this rejection.

Claim 1 recites "more than 70% similar, preferably more than 80% similar, ... most preferably more than 97% similar" and "more than 70% identical, preferably more than 80% identical, ... most preferably more than 97% identical." It is unclear what level of similarity or identity is ultimately required by the claim, the lowest or highest percentage. See also claim 17. Applicant's response did not address this rejection.

Claim 1 recites "functional fragment or complement thereof for the preparation of a medicament for treating diseases associated with yeast or fungi." It is unknown from the specification what particular structural or functional characteristics define a functional fragment or complement that could be used in this way. Applicant's response did not address this rejection.

Claim 10 is confusing in reciting "selected from the group consisting of ... or." It appears that improper Markush language has been used. Applicant's response did not address this rejection.

Claim 17 is confusing in reciting "involved in a pathway for programmed cell death of yeast or fungi." It is unclear if each of the nucleic acids encompassed by the claim (e.g. having particular levels of identity or similarity, those encoding a functional equivalent, derivative or

bioprecursor) must have this characteristic. It is unclear what particular activity would meet the limitation of "involved in a pathway." Applicant's response did not address this ground of rejection.

Claim 18 is confusing in depending upon claim 16 which is a non-elected claim. Claim 16 is directed to a method of treating infection. This appears to be typographical error. Applicant's response did not address this rejection.

Claim 19 is confusing in reciting "selectively hybridizing." It is unclear what degree of hybridization would meet this limitation. Applicant's response did not address this rejection.

Claims 26-27 are confusing in that the vector elements recited are not operably linked or in any way associated with the nucleic acid of claim 17. See also claims 50-51. Applicant's response did not address this rejection.

Claims 49 and 53 are confusing in reciting a "human homologue." It is unclear what functional or structural characteristics define a human homologue. That is, must the sequence have a particular level of identity, similarity, or some other feature? In addition, claim 53 recites "human homologue of at least one of the nucleic acid sequences." It is unclear what applicant intends by this language. Must the sequence have a particular level of identity, similarity, or some other feature to multiple sequences? Applicant's response did not address this rejection.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Marianne P. Allen
Primary Examiner
Art Unit 1631

10/12/04

mpa